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### REMARKS

#### I. Petition for Extension of Time

Applicant herewith petitions the Commissioner for Patents to extend the time for response to the Office Action mailed 28 September 2007 for three (3) months from 28 December 2007 to 28 March 2008. Authorization is given to charge the extension of time fee ✓ of \$1020.00 (37 C.F.R. §1.136 and §1.17) to Deposit Account No. 23-1703. Any deficiency or overpayment should be charged or credited to the above numbered deposit account.

#### II. Claim amendments

To clarify the claimed invention, the recitation of "lipids" has been deleted from the Markush group of surface active agents in claims 1-4. Support is provided by paragraphs [0058]-[0064] of the published patent application US 2005-0238719 A1 which discloses examples of suitable active agents for use in the claimed film coating composition.

Applicant submits that no new matter has been introduced by the claim amendments.

#### III. Claim Rejections – 35 U.S.C. §102

Claims 3 and 5 are rejected under 35 U.S.C. §102(b) as allegedly being anticipated by the publication to Petereit et al., European Journal of Pharmaceutics and Biopharmaceutics, Vol. 41, No. 4, pp. 219-228 ("Petereit").

Petereit discloses film-coating compositions containing Eudragit and GMS. Petereit describes GMS as an anti-sticking agent (Petereit at paragraph 2.3) and as a lipophilic surfactant (Petereit at paragraph 2.4).

GMS is the anti-sticking agent of the claimed film-coating composition. However, according to amended claims 1-4, the surface active agent cannot be GMS. Specifically, with reference to claims 1-4, the surface active agent of the claimed invention is selected from the group consisting of nonionic surfactants, ampholytic surfactants, anionic surfactants, soaps, fatty acids and their salts. GMS is a nonionic surfactant. But GMS is none of the other surface active agents listed in the Markush group. Furthermore, when the surface active agent of the claimed invention is a nonionic surface agent, the Markush group does not include GMS which is not a

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sorbitan ester, polysorbate, polyoxyethylated glycol monoether, polyoxyethylated alkyl phenol, alkyl glucoside, sugar fatty acid ester or a saponin.

In view of the foregoing clarification, it is evident that the claimed invention requires a surface active agent which is not GMS. Accordingly, it is irrelevant if GMS acts as both an anti-sticking agent and surface active agent as disclosed by Petereit. The fact remains that the claimed invention requires GMS as the anti-sticking agent and a surface active agent which is not GMS. Petereit fails to disclose this feature of the claimed invention.

For all of the foregoing reasons, Petereit fails to anticipate the claimed invention. Withdrawal of the §102 rejection is requested.

#### **IV. Claim Rejections – 35 U.S.C. §103**

Claims 3-9 are rejected under 35 U.S.C. §103(a) as being unpatentable over Petereit in view of WO 02/058677 ("Hölzer").

Hölzer has a publication date of 1 August 2002 which is the Swedish priority date of the subject application. Accordingly, Hölzer does not qualify as prior art. In any event, Applicant submits that Hölzer does not overcome the deficiencies of the primary reference to Petereit as discussed in the preceding Section III. Specifically, even if Hölzer qualified as prior art which Applicant does not admit, neither Petereit nor Hölzer, whether taken alone or in combination, suggests the claimed invention.

For all of the foregoing reasons, the combination of Petereit and Hölzer fails to establish a *prima facie* case of obviousness. Withdrawal of the §103 rejection is requested.

#### **V. Restriction Requirement**

Applicant is appreciative of the rejoinder of Group IV. However, Applicant repeats that the restriction of Groups V and VI is contrary to the relevant regulations governing restriction practice with regard to national stage applications.

The referenced application is a national stage application. According to 37 C.F.R. §1.475 (b)(1), "...a national stage application containing claims to different categories of invention will be considered to have unity of invention if the claims are drawn only to one of the following combinations of categories: (1) A product and a process specially adapted for the manufacture of

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said product". Withdrawn Groups V and VI are directed to processes for the preparation of the pharmaceutical formulations of elected and rejoined Groups III and IV, respectively.

Furthermore, for the reasons given above, Petereit no longer supports the restriction requirement of record.

Therefore, in view of the claim amendments and fact that Petereit no longer supports the restriction requirement of record, Applicant respectfully requests the Examiner to exercise his discretion and reconsider the restriction requirement with respect to Groups V and VI. In view of 37 C.F.R. §1.475(b)(1), there is unity of invention between Groups III-VI, i.e., a product and a process specially adapted for the manufacture of said product.

### CONCLUSION

Applicant has made a good faith attempt to respond to the Office Action. Petereit fails to anticipate claims 3 and 5. Hölzer does not qualify as prior art relative to the subject application. As such, the cited combination of Petereit and Hölzer fails to support the obviousness rejection of claims 3-9. Applicant requests reconsideration of the restriction requirement. Applicant relies on 37 C.F.R. §1.475(b)(1) and requests at least the rejoinder of the related product and process claims of Groups III-VI.

Any fee due in connection with this communication should be charged to Deposit Account No. 23-1703.

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Respectfully submitted,



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